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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,949	02/20/2004	Anthony M. Ging	4398-286	9703
23117 7590 09/20/2007 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			EXAMINER PATEL, NIHIR B	
			ART UNIT 3772	PAPER NUMBER
			MAIL DATE 09/20/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/781,949

Applicant(s)

GING ET AL.

Examiner

Nihir Patel

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3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07.09.2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-12 and 19-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 and 4-6 is/are allowed.
- 6) ☒ Claim(s) 7-12 and 19-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed on July 9th, 2007 have been fully considered but they are not persuasive. The applicant argues that Palkon does not disclose or suggest an inwardly sloping or stepped outer wall between the membranes and the frame engaging portion of the cushion. The examiner disagrees. Figures 3, 4 and 5 of Palkon clearly show an inwardly sloping or stepped outer wall between the membrane and the frame engaging portion of the cushion.
2. Claims 1 and 4-6 are allowed as stated in the previous office action dated April 10th, 2007. The examiner also acknowledges the cancellation of claims 2, 3 and 13 and withdrawal of claims 14-18 and 28.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims **7, 13, 19 and 25-27** are rejected under 35 U.S.C. 102(e) as being anticipated by Palkon et al. (US 7,007,696).
5. **As to claim 7**, Palkon discloses a nasal/respiratory mask that comprises an outer membrane **31** including a face-contact portion to form a seal with the patent; a frame connection portion opposite of the face contact portion (**see figures 1 and 2**); an inwardly sloping or stepped outer wall between the outer membrane and the frame connection portion (**see figures 1-5**) an

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underlying rim **47a** positioned below the membrane (**see figures 6 and 7**), wherein the membrane and the rim formed and positioned with respect to one another to accommodate at least one of a pre-adult patient or a small sized adult patient and the cushion includes a nasal bridge region **38**, a top lip region **39** and two side regions **40** (**see figure 3**).

6. **As to claim 13**, Palkon teaches an apparatus wherein the frame connection portion **32** is provided opposite the face contact portion (**see figures 1-3**), wherein the cushion has a generally stepped and/or sloped profile such that a projected area of the frame connection portion is generally larger than an area defined by the face contact portion of the membrane (**see figures 3 and 4**).

6. **As to claims 19 and 25-27**, Palkon teaches an apparatus wherein the membrane and the rim are formed and positioned with respect to one another (**see figures 6 ad 7**) that is capable to accommodate a pre-adult patient aged 16 years or less.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
9. Claims **8-12 and 20-24** are rejected under 35 U.S.C. 103(a) as being unpatentable over Palkon et al. (US 7,007,696).
10. **As to claim 8**, Palkon substantially discloses the claimed invention, see rejection of claim 7 above, but does not disclose a width of the membrane orifice being between 30 and 32mm in the lip region, between about 18 and 20mm in each side region, and between about 22 and 24mm in the nasal bridge region, a width of the rim orifice being about 34 and 36mm in the nasal bridge region, between about 32 and 34mm in the lip region, and between about 42 and 44mm in each of the side regions of the cushion, the membrane height that is about 27 and 35mm in the nasal region, between about 19 and 22mm in the lip region, and between about 33-35mm in each side regions, the rim height being between about 13 and 18mm in the nasal bridge region and the lip region and the rim height in each of the side portions being between 25-27mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Palkon's invention by providing a width of the membrane orifice being between 30 and 32mm in the lip region, between about 18 and 20mm in each side region, and between about 22 and 24mm in the nasal bridge region, a width of the rim orifice being about 34 and 36mm in the nasal bridge region, between about 32 and 34mm in the lip region, and between about 42 and 44mm in each of the side regions of the cushion, the membrane height that is about 27 and 35mm in the nasal region, between about 19 and 22mm in the lip region, and between about 33-35mm in each side regions, the rim height being between about 13 and 18mm in the nasal bridge region and the lip region and the rim height in each of the side portions being between 25-27mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering

the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

11. As to claims 9 and 22, Palkon substantially discloses the claimed invention, see rejection of claim 7 above, but does not disclose an aperture having a width between about 30-42mm, an effective height as vertically measured from an edge of the rim to a top of the cushion as seen in plan view of between about 32-42mm, and an effective bridge depth of between about 13-24mm as vertically measured from the membrane in the nasal bridge region to the rim in each side region in top view. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Palkon's invention by providing an aperture having a width between about 30-42mm, an effective height as vertically measured from an edge of the rim to a top of the cushion as seen in plan view of between about 32-42mm, and an effective bridge depth of between about 13-24mm as vertically measured from the membrane in the nasal bridge region to the rim in each side region in top view, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

12. As to claims 10 and 23, Palkon substantially discloses the claimed invention, see rejection of claim 7 above, but does not disclose a width that is between about 39-40mm, the height is about 35mm and the depth is less than about 15mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Palkon's invention by providing a width that is between about 39-40mm, the height is about 35mm and the depth is less than about 15mm, since it has been held that where the general conditions of a claim are

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disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

13. As to claims 11 and 24, Palkon substantially discloses the claimed invention, see rejection of claim 7 above, but does not disclose a width that is between about 34-35mm, the height is about 40mm and the depth is about 20mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Palkon's invention by providing a width that is between about 34-35mm, the height is about 40mm and the depth is about 20mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

14. As to claim 12, Palkon substantially discloses an apparatus that comprises a membrane that generally follows a contour of the rim (see figures 6 and 7).

15. As to claim 20, Palkon substantially discloses the claimed invention, see rejection of claim 7 above, but does not disclose a width of the membrane orifice being between 30 and 32mm in the lip region, between about 18 and 20mm in each side region, and between about 22 and 24mm in the nasal bridge region, a width of the rim orifice being about 34 and 36mm in the nasal bridge region, between about 32 and 34mm in the lip region, and between about 42 and 44mm in each of the side regions of the cushion. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Palkon's invention by providing a width of the membrane orifice being between 30 and 32mm in the lip region, between about 18 and 20mm in each side region, and between about 22 and 24mm in the nasal bridge region, a width of the rim orifice being about 34 and 36mm in the nasal bridge region,

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between about 32 and 34mm in the lip region, and between about 42 and 44mm in each of the side regions of the cushion, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

16. As to claim 21, Palkon substantially discloses the claimed invention, see rejection of claim 7 above, but does not disclose a membrane height that is about 27 and 35mm in the nasal region, between about 19 and 22mm in the lip region, and between about 33-35mm in each side regions, the rim height being between about 13 and 18mm in the nasal bridge region and the lip region and the rim height in each of the side portions being between 25-27mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Palkon's invention by providing a membrane height that is about 27 and 35mm in the nasal region, between about 19 and 22mm in the lip region, and between about 33-35mm in each side regions, the rim height being between about 13 and 18mm in the nasal bridge region and the lip region and the rim height in each of the side portions being between 25-27mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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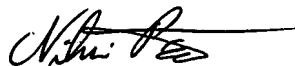
the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Nihir Patel



MICHAEL A. BROWN
PRIMARY EXAMINER